IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Stephen J. Brown
Serial No.:	09/496,893
Title:	SYSTEM AND METHOD FOR IDENTIFYING DISEASE-INFLUENCING GENES
Filed:	February 2, 2000
Attorney Docket No.:	00-0220 / 7553.00030
Examiner:	Smith, C.
Art Unit:	1631

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal by an attorney either of record or acting under 37 CFR 1.34.

REMARKS

Review is requested for the following reasons:

The Examiner has clearly made the following errors with respect to the rejection of claims 83-93 under 35 U.S.C. §112, second paragraph. The Office Action does not factually establish that a person of ordinary skill in the relevant art could not interpret the metes and bounds of claims 83 and 90 so as to understand how to avoid infringement (see MPEP §2173.02). Specifically, the Office Action fails to explain why a person of ordinary skill in the relevant art would be unable to reasonably discern a relationship between the preamble and the method steps when the claim is read in light of the specification. Furthermore, the Office Action does not present any suggestions to improve the language (as suggested under MPEP §2173.02) or any prior art rejection showing that at least one interpretation would render the claim unpatentable over the prior art.

In contrast to the position taken in the Office Action, the specification provides:

> The second group of genomics companies takes a more epidemiological approach by first researching families or groups of individuals having a similar disease, and then isolating the relevant genes. In this method, also known as positional cloning, blood samples are taken from the individuals and analyzed. The blood samples contain DNA, which is studied to identify certain regions of the genome which appear to be associated with the disease. Linking a region of the genome with a disease is known as linkage analysis or genetic linkage mapping. Once a region of the genome has been identified, it is sequenced via targeted discovery gene sequencing (page 5, lines 5-15 of the specification).

The relationship between the preambles and bodies of claims 83 and 90 can be clearly ascertained when read in light of the above paragraph, as illustrated in the following table.

Specification Example	Claim 83	Claim 90
concerns a method for isolating genes that are relevant to a disease for sequencing	concerns a method for selecting one or more disease-influencing genes needed to be processed for medical research	Concerns a system for selecting one or more disease-influencing genes needed to be processed for medical research
researching groups of individuals having a similar disease	selecting individuals having a risk factor for a disease; providing to each individual a communications apparatus; sending queries to each individual through the apparatus; receiving responses to the queries from the apparatus; storing the responses of each individual; defining a plurality of groups by categorizing the individuals having similar profiles based on the responses;	a communications apparatus operable by an individual; and a communication network in signal communication with the communications apparatus and a server, a workstation configured to send scripted queries, a genotyping system configured to provide genotype information of the individual, and a patient profile system configured to receive responses from the individual and genotype information analyses via the communications network and the server,
using blood samples to get genomic information for the individuals, and identifying certain regions of the genomes of the individuals which appear to be associated with the disease	receiving genotype information for the individuals and comparing the genotype information between groups, and generating a report for presentation on a display that represents a subset of the genotype information	whereby the genotype information is compared based upon groups formed using the responses to the scripted queries in the patient profile system to identify one or more individuals having a disease-influencing gene

Furthermore, the arguments presented on page 16, line 10 through page 18, line 15 of the Response After Final, filed November 28, 2007, are herein incorporated by reference. As such, the rejection of claims 83-93 under 35 U.S.C. §112, second paragraph, does not appear to be sustainable and should be withdrawn.

The Examiner has clearly made the following errors with respect to the rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, as not having adequate written description. The arguments presented on page 7, line 16 through page 12, line 8 of the Response After Final, filed November 28, 2007, are herein incorporated by reference. Furthermore, further written support for the phrases "selecting one or more disease-influencing genes needed to be processed for medical research" (e.g., isolating the relevant genes) and "that represents a subset of the genotype information" (e.g., identify certain regions of the genome which appear to be associated with the disease) can also be found in the paragraph on page 5, lines 5-15 of the specification, which is presented above in connection with the §112, second paragraph, rejection of claims 83-93.

Furthermore, in response to the Examiner's assertion that the scope of the phrase "processed for medical research" also encompasses activities such as clinical trials, developing pharmaceuticals and kits, diagnosing disease, etc. (see page 2 of the Advisory Action), lines 1-5 on page 36 of the specification states "Moreover, the invention is not limited to the specific applications described. The system and method of the invention have many other applications. For example, pharmaceutical manufacturers may apply the system in clinical trials to analyze new drug data." As such, the rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, with respect to the "written description" requirement does not appear to be sustainable and should be withdrawn.

The Examiner has clearly made the following errors with respect to the rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, as not being enabled. The arguments presented on page 12, line 9 through page 16, line 9 of the Response After Final, filed November 28, 2007, are herein incorporated by reference. Furthermore, even assuming gene sequencing as an art is considered unpredictable (as urged by the Examiner and for which Applicant's representative does not necessarily agree), the Examiner has not clearly explained why a person of ordinary skill in the

field of the invention would view the expressly recited steps in claim 83 as being unpredictable. As such, the rejection of claims 83-98 under 35 U.S.C. §112, first paragraph, with respect to the "enablement" requirement does not appear to be sustainable and should be withdrawn.

Applicants' representative believes that clear errors in the Examiner's rejection(s) exist or the Examiner has omitted one or more essential elements needed for a *prima facie* rejection.

The Examiner is respectfully invited to call the Applicants' representative should it be deemed beneficial to further advance prosecution of the application.

If any additional fees are due, please charge Deposit Account No. 50-0541.

Respectfully submitted,

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Dated: January 28, 2008

c/o Sandeep Jaggi
Health Hero Network

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